PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mien-Chie Hung *et al.*	§	Group Art Unit: Unassigned
Serial No.: Unassigned	§	Examiner: Unassigned
Filed: Concurrently Herewith	§	Atty. Dkt. No.: UTSC:484USC1/MBW
For: SENSITIZATION OF HER-2/NEU OVEREXPRESSING CANCER CELLS TO CHEMOTHERAPY	§	

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PRELIMINARY AMENDMENT

Commissioner of Patents
Washington, D.C. 20231

Sir:

Please amend this application as follows:

In the Specification:

Amend the specification by inserting before the first line the sentence: --This is a continuation of co-pending application Serial No. 08/809,021 filed March 19, 1997--.

In the claims:

Please cancel claims 1-75 without prejudice or disclaimer and add the following claims:

76. (New) A method for suppressing growth of a tumor comprising a *neu* oncogene cell, comprising contacting the cell in the tumor with an E1A gene product and a chemotherapeutic drug in amounts effective to suppress growth of the tumor.

77. (New) The method of claim 76, wherein growth of the tumor is *neu* oncogene-mediated.

78. (New) The method of claim 76, wherein the chemotherapeutic drug is an alkylating agent, a plant alkaloid, an antibiotic or an antineoplastic agent.

79. (New) The method of claim 78, wherein the chemotherapeutic drug is an alkylating agent.

80. (New) The method of claim 79, wherein the alkylating agent is mechlorethamine, cyclophosphamide, ifosfamide chlorambucil, melphalan, busulfan, thiotepa, carmustine, lomustine, or streptozocin.

81. (New) The method of claim 78, wherein the chemotherapeutic drug comprises a plant alkaloid.

82. (New) The method of claim 81, wherein the plant alkaloid is vincristine, vinblastine or paclitaxel.

83. (New) The method of claim 82, wherein the plant alkaloid is vincristine.

84. (New) The method of claim 82, wherein the plant alkaloid is vinblastine.

85. (New) The method of claim 82, wherein the plant alkaloid is paclitaxel.

86. (New) The method of claim 78, wherein the chemotherapeutic drug is an antibiotic.

87. (New) The method of claim 86, wherein the antibiotic is dactinomycin, daunorubicin, idarubicin, bleomycin, mitomycin, or doxorubicin.

88. (New) The method of claim 87, wherein the antibiotic is dactinomycin.

89. (New) The method of claim 87, wherein the antibiotic is daunorubicin.

90. (New) The method of claim 87, wherein the antibiotic is idarubicin.

91. (New) The method of claim 87, wherein the antibiotic is bleomycin.

92. (New) The method of claim 87, wherein the antibiotic is mitomycin.

93. (New) The method of claim 87, wherein the antibiotic is doxorubicin.

94. (New) The method of claim 78, wherein the chemotherapeutic drug is an antineoplastic agent.

95. (New) The method of claim 94, wherein the antineoplastic agent is selected from the group consisting of cisplatin, VP16, and TNF.

96. (New) The method of claim 95, wherein the antineoplastic agent is cisplatin.

97. (New) The method of claim 95, wherein the antineoplastic agent is VP16.

98. (New) The method of claim 95, wherein the antineoplastic agent is TNF.

99. (New) The method of claim 76, wherein the E1A gene product is introduced to the cell prior to the administration of the chemotherapeutic drug.

100. (New) The method of claim 76, wherein the chemotherapeutic drug is administered to the cell prior to introduction of the E1A gene product.

101. (New) The method of claim 76, wherein the E1A gene product is introduced to the cell and the chemotherapeutic drug is administered to the cell substantially simultaneously.

102. (New) The method of claim 76, wherein the cell is located within an animal and effective amounts of the E1A gene product and the chemotherapeutic drug are administered to the animal.

103. (New) The method of claim 76, wherein the chemotherapeutic drug is suitably dispersed in a pharmacologically acceptable formulation.

104. (New) The method of claim 76, wherein the cell is contacted with a single composition for introducing the E1A gene product and administering the chemotherapeutic drug.

105. (New) The method of claim 104, wherein the composition is suitably dispersed in a pharmacologically acceptable formulation.

106. (New) The method of claim 76, wherein the E1A gene product is introduced into the cell by introduction of a nucleic acid encoding the E1A gene product and obtaining expression of the E1A gene product.

107. (New) The method of claim 106, wherein the E1A gene product is the E1A 12S or 13S gene product.

108. (New) The method of claim 106, wherein the E1A gene product is either the E1A 12S or 13S gene product.

109. (New) The method of claim 106, wherein the E1A gene encodes both the E1A 12S and 13S gene products.

110. (New) The method of claim 106, wherein the gene encoding the E1A gene product is introduced into the cell by introduction of an adenovirus.

111. (New) The method of claim 106, wherein the gene encoding the E1A gene product encodes a mini-E1A gene product.

112. (New) The method of claim 106, wherein the gene encoding the E1A gene product is introduced into the cell using an E1A nucleic acid/lipid complex.

113. (New) The method of claim 112, wherein the lipid comprises DOTMA, DOPE, or DC-Chol.

114. (New) The method of claim 112, wherein the lipid comprises DC-Chol.

115. (New) The method of claim 112, wherein the lipid comprises DC-Chol and DOPE.

116. (New) The method of claim 112, wherein the DNA/lipid complex is administered by injection.

117. (New) The method of claim 106, wherein the E1A gene product is introduced into the cell by introduction of a vector containing a gene encoding the E1A gene product.

118. (New) The method of claim 117, wherein the vector is a viral vector.

119. (New) The method of claim 118, wherein the vector is an adenoviral vector.

120. (New) The method of claim 117, wherein the cell is a human cell.

121. (New) The method of claim 120, wherein the cell is a lung cancer cell.

122. (New) A method for suppressing growth of a *neu*-mediated cancer in an animal having or suspected of having the cancer comprising administering to the animal an effective combination of E1A gene product and chemotherapeutic drug in an effective amount to suppress growth of the cancer.

123. (New) The method of claim 122, wherein growth of the cancer is *neu* oncogene-mediated.

124. (New) The method of claim 122, wherein the animal is a mammal.

125. (New) The method of claim 124, wherein the mammal is a human.

126. (New) The method of claim 125, wherein the cancer is lung cancer.

127. (New) The method of claim 122, wherein the chemotherapeutic drug is an alkylating agent, a plant alkaloid, an antibiotic or an antineoplastic agent.

128. (New) The method of claim 127, wherein the chemotherapeutic drug is an alkylating agent.

129. (New) The method of claim 128, wherein the alkylating agent is mechlorethamine, cyclophosphamide, ifosfamide chlorambucil, melphalan, busulfan, thiotepa, carmustine, lomustine, or streptozocin.

130. (New) The method of claim 127, wherein the chemotherapeutic drug comprises a plant alkaloid.

131. (New) The method of claim 130, wherein the plant alkaloid is vincristine, vinblastine or paclitaxel.

132. (New) The method of claim 131, wherein the plant alkaloid is vincristine.

133. (New) The method of claim 131, wherein the plant alkaloid is vinblastine.

134. (New) The method of claim 131, wherein the plant alkaloid is paclitaxel.

135. (New) The method of claim 127, wherein the chemotherapeutic drug is an antibiotic.

136. (New) The method of claim 135, wherein the antibiotic is dactinomycin, daunorubicin, idarubicin, bleomycin, mitomycin, or doxorubicin.

137. (New) The method of claim 136, wherein the antibiotic is dactinomycin.

138. (New) The method of claim 136, wherein the antibiotic is daunorubicin.

139. (New) The method of claim 136, wherein the antibiotic is idarubicin.

140. (New) The method of claim 136, wherein the antibiotic is bleomycin.

141. (New) The method of claim 136, wherein the antibiotic is mitomycin.

142. (New) The method of claim 136, wherein the antibiotic is doxorubicin.

143. (New) The method of claim 127, wherein the chemotherapeutic drug is an antineoplastic agent.

144. (New) The method of claim 143, wherein the antineoplastic agent is selected from the group consisting of cisplatin, VP16, and TNF.

145. (New) The method of claim 144, wherein the antineoplastic agent is cisplatin.

146. (New) The method of claim 144, wherein the antineoplastic agent is VP16.

147. (New) The method of claim 144, wherein the antineoplastic agent is TNF.

148. (New) The method of claim 122 comprising introducing into the animal a therapeutically effective amount of an E1A gene product and contacting the animal with a chemotherapeutic drug.

149. (New) The method of claim 122, wherein a cancer site is contacted with a chemotherapeutic drug by administering to the animal a therapeutically effective amount of a pharmaceutical composition comprising a chemotherapeutic drug.

150. (New) The method of claim 122, wherein the E1A gene product is administered via the introduction of a gene encoding the E1A gene product and obtaining expression of the E1A gene product.

151. (New) The method of claim 150, wherein the E1A gene product is administered by introducing to the animal a nucleic acid encoding the E1A gene product and obtaining expression of the E1A gene product.

152. (New) The method of claim 151, wherein the E1A gene product is the E1A 12S or 13S gene product.

153. (New) The method of claim 151, wherein the E1A gene product is either the E1A 12S or 13S gene product.

154. (New) The method of claim 151, wherein the E1A gene encodes both the E1A 12S and 13S gene products.

155. (New) The method of claim 151, wherein the gene encoding the E1A gene product is introduced to the animal by introduction of an adenovirus.

156. (New) The method of claim 151, wherein the gene encoding the E1A gene product encodes a mini-E1A gene product.

157. (New) The method of claim 151, wherein the gene encoding the E1A gene product is introduced to the animal using an E1A nucleic acid/lipid complex.

158. (New) The method of claim 157, wherein the lipid comprises DOTMA, DOPE, or DC-Chol.

159. (New) The method of claim 157, wherein the lipid comprises DC-Chol.

160. (New) The method of claim 157, wherein the lipid comprises DC-Chol and DOPE.

161. (New) The method of claim 157, wherein the DNA/lipid complex is administered by injection.

162. (New) The method of claim 151, wherein the E1A gene product is administered by introducing to the animal a vector containing a gene encoding the E1A gene product.

163. (New) The method of claim 162, wherein the vector is a viral vector.

164. (New) The method of claim 163, wherein the vector is an adenoviral vector.

165. (New) A pharmaceutical composition comprising nucleic acid encoding an E1A gene product and a chemotherapeutic drug.

166. (New) The composition of claim 165, wherein the chemotherapeutic drug is an alkylating agent, a plant alkaloid, an antibiotic or an antineoplastic agent.

167. (New) The composition of claim 166, wherein the chemotherapeutic drug is an alkylating agent.

168. (New) The composition of claim 167, wherein the alkylating agent is mechlorethamine, cyclophosphamide, ifosfamide chlorambucil, melphalan, busulfan, thiotepa, carmustine, lomustine, or streptozocin.

169. (New) The composition of claim 166, wherein the chemotherapeutic drug comprises a plant alkaloid.

170. (New) The composition of claim 169, wherein the plant alkaloid is vincristine, vinblastine or paclitaxel.

171. (New) The composition of claim 170, wherein the plant alkaloid is vincristine.

172. (New) The composition of claim 170, wherein the plant alkaloid is vinblastine.

173. (New) The composition of claim 170, wherein the plant alkaloid is paclitaxel.

174. (New) The composition of claim 166, wherein the chemotherapeutic drug is an antibiotic.

175. (New) The composition of claim 174, wherein the antibiotic is dactinomycin, daunorubicin, idarubicin, bleomycin, mitomycin, or doxorubicin.

176. (New) The composition of claim 175, wherein the antibiotic is dactinomycin.

177. (New) The composition of claim 175, wherein the antibiotic is daunorubicin.

178. (New) The composition of claim 175, wherein the antibiotic is idarubicin.

179. (New) The composition of claim 175, wherein the antibiotic is bleomycin.

180. (New) The composition of claim 175, wherein the antibiotic is mitomycin.

181. (New) The composition of claim 175, wherein the antibiotic is doxorubicin.

182. (New) The composition of claim 166, wherein the chemotherapeutic drug is an antineoplastic agent.

183. (New) The composition of claim 182, wherein the antineoplastic agent is selected from the group consisting of cisplatin, VP16, and TNF.

184. (New) The composition of claim 183, wherein the antineoplastic agent is cisplatin.

185. (New) The composition of claim 183, wherein the antineoplastic agent is VP16.

186. (New) The composition of claim 183, wherein the antineoplastic agent is TNF.

187. (New) The pharmaceutical composition of claim 165, wherein the nucleic acid encoding the E1A gene product and the chemotherapeutic drug are comprised in the same pharmaceutical composition.

188. (New) A therapeutic kit comprising, a pharmaceutical formulation of an E1A gene product and a pharmaceutical formulation of a chemotherapeutic drug.

189. (New) The kit of claim 188, wherein the pharmaceutical formulation of an E1A gene product and the pharmaceutical formulation of a chemotherapeutic drug are present within distinct containers.

REMARKS

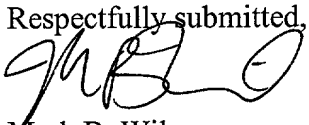
The active claims in this case are claims 76 - 189.

The specification has been amended to recite the relationship with the parent case.

A fee as set forth in 37 C.F.R. §§ 1.61-1.21 in the amount of $1,241.00 is enclosed. If an appropriate check has not been enclosed, or if it is insufficient under 37 C.F.R. §§ 1.61-1.21, the Commissioner is hereby authorized to deduct any necessary fees from Fulbright & Jaworski Deposit Account No. 50-1212/10105728/MBW.

Should Examiner Crouch have any questions regarding this communication, she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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